

REMARKS

A paragraph has been added to the specification to describe the benefits of using recessed cross members. This subject matter is not new matter. The reviewing courts have held that the advantages that an invention provides may be added to a specification without raising new matter issues.¹ The specification also has been amended to clearly describe the stationary portion of the flexible flap. Claims 63-71 have been added to this application. Thus, claims 33-71 are now pending in this case.

Claims 33-62 of this application have been noted as conflicting with claims in other pending applications that applicants have before the United States Patent and Trademark Office. Applicants respectfully submit that the claims that are pending in this application do not conflict with any of the claims that are present in those applications. To the extent that there is a conflict, however, applicants will either cancel those claims or file a Terminal Disclaimer to overcome any double patenting rejection that may exist in this case when it is otherwise in condition for allowance.

Claims 33-56 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.K. Patent Application GB 2,072,516A to Simpson in view of U.S. Patent 3,191,618 to McKim. Applicants respectfully submit that this rejection cannot be sustained.

In making this obviousness rejection, the Examiner correctly indicates that Simpson does not describe a flexible flap that is secured to the valve seat at two securement points. There is, however, another notable difference between applicants' claimed invention and the Simpson disclosure. Applicants' invention also requires that the "flexible flap be positioned on the valve seat such that the flap is pressed towards the seal surface in an abutting relationship therewith when a fluid is not passing through the orifice."

Simpson shows two different valves, neither of which shows these features of applications' invention:

¹ *In re Davies*, 177 USPQ 381, 385 (CCPA 1973) ("the public will derive the most benefit from a patent when it discloses on its face those properties or utilitarian advantages which were ultimately persuasive on the question of nonobviousness...we see no impediment to the present appellants'...incorporating a discussion of the allegedly unobvious properties while retaining the effective date of the application involved here.").

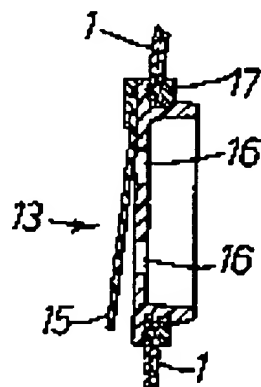


FIG. 2.

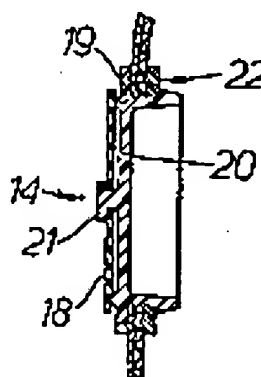


FIG. 3.

As stated, Simpson does not teach or suggest how to position the flexible flap on the valve seat such that the flap that is pressed towards the seal surface in an abutting relationship with it under neutral conditions. An expert in the field of respirators and respirator components, David M. Castiglione, in his February 2, 2001 Affidavit (copy attached), has provided evidence that establishes that the valve 13 shown in Figure 2 of Simpson does not have its flap positioned on the valve seat such that the flap 15 is pressed towards the seal surface in an abutting relationship with it when a wearer is neither inhaling nor exhaling. Castiglione states that "there is nothing that can be discerned from Figure 2 or from the specification that would indicate that the flap is pressed towards the seal surface in its neutral position." Castiglione explains that the mounting of the Simpson flap at the top or fixed portion would cause no force or preload to be exerted upon the flap. Such a force is needed to bias the flap or otherwise cause it to be pressed against the seal surface. As the above-reproduced FIG. 2 illustrates, the flap 15 on valve 13 would at best be in mere contact with the seal surface when a wearer is neither inhaling nor exhaling. Such a structure cannot provide the benefits that applicants' invention provides, namely, the ability to keep the valve hermetically sealed under any orientation of the valve.

Simpson's valve provides protection to the wearer only at the most critical time — during an inhalation. When a wearer of the Simpson mask inhales, the flap becomes firmly pressed against the seal surface by virtue of the negative pressure inside the mask. But when the wearer is neither inhaling nor exhaling, and has their head tilted downward, the possibility exists that contaminants can enter the mask interior when the flap droops downwardly away from the seal surface. Unlike Simpson, applicants teach persons of ordinary skill how to make a low pressure

drop, flapper-style exhalation valve that will preclude contaminant influx under all orientations of the mask. The failure to appreciate the advantages that applicants' invention provides, further established its nonobviousness.² In short, Simpson does not teach the positioning of the flap to allow it to be pressed against the seal surface of applicants' valve, and it does not appreciate the benefits that can stem from this aspect of applicants' invention.

In addition, Simpson does not indicate that the flap 18 in Figure 3 is pressed against the seal surface. Unlike the Figure 2 flap 15, the Figure 3 flap 18 is shown to be flush against the seal surface, but there is nothing to indicate that the flap is pressed against that surface. If such were the case, you would expect Simpson to show the flap 18 as being in an at least slightly curved configuration. A planar flap would not be pressed against the seal surface unless it was already prestressed or curved in a concave configuration. Simpson's flap resides in a perfectly linear configuration when at rest, and there is nothing in the text that otherwise suggests that it is prestressed. Thus, Simpson's button-style valve 14, even though not nearly as pertinent to applicants' invention as its flapper valve 13, also is not pressed towards the seal surface.³

Simpson also does not disclose a flexible flap that is secured to the valve seat at the stationary portion of the flap at two securement points. Although the Examiner recognizes this fact, McKim is improperly relied on as a secondary reference for finding the applicants' invention to have been obvious to a person of ordinary skill.

The record does not present any evidence that the disclosures in Simpson and McKim are combinable. As the Examiner is aware, there must be some teaching or suggestion or knowledge generally available that would have led a person of ordinary skill to combine the pertinent disclosures in two separate documents.⁴

² *In re Fine*, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988).

³ Simpson's Figure 3 valve 14 is a button-style valve that is centrally mounted at a hub 21. Button-style valves do not have a peripheral edge that includes a stationary segment and a free segment. Nor do they have opposing stationary and free ends. In button-style valves, the whole peripheral edge is free to be lifted from the seal surface (Simpson, lines 58-61). These valves are disadvantageous in that the central mounting does not provide the large moment arm that flapper-style valves can provide. The limitations recited in applicants' independent claims under (b) (2) (iii) describe a flapper-style system and not a button-style system.

⁴ *In re Fine* at 1599 ("Obviousness is tested by 'what the combined teachings of the references would have suggested to those of ordinary skill in the art.' But it 'cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination.' And 'teachings of references can be combined *only* if there is some suggestion or incentive to do so.' Here, the prior art contains none." (citation omitted)).

A probable reason why the record lacks any evidence that the McKim teachings are combinable with Simpson is because McKim is directed to a field entirely different from the field of exhalation valves for respirators.

McKim describes a curved seat reed valve that is designed for use in a two-cycle, high-speed engine which would turn at extremely high rpms — that is, at speeds as high as 10,000 or 12,000 revolutions per minute. This kind of technology would not be used by a person of ordinary skill in designing an exhalation valve for a respirator. McKim's valve is particularly suited for rapid operation where opening and closing forces are large. These forces can cause the valve to bounce (an elastic recoil from impact). The stated goals in McKim are full rapid-opening, quick and complete closing, and eliminating float or bounce. McKim's valve operates when a piston in the engine's cylinder moves from a top dead center to a bottom dead center, and the pressure within the crank case is reduced below atmospheric to overcome the spring bias of the valve reed. Castiglione explained why persons of ordinary skill in his field do not consult reed valves for high-speed engines when developing exhalation valves for face masks:

A filtering face mask is worn over the nose and mouth of a person for filtering contaminants that may be present in ambient air. Filtering face masks commonly employ exhalation valves to allow more moist exhaled air to be rapidly purged from the mask interior. The exhalation valves are used to improve wearer comfort. These valves operate at normal room temperatures and low pressures. The field of endeavor for a filtering face mask is very different from the field of endeavor of a curved seat reed valve that is used in a high-speed engine. Persons of ordinary skill in the field of designing filtering face masks do not consult documents that describe valves for gasoline engines in developing respiratory products. Exhalation valves for respirators operate under very different conditions from valves that are used in gasoline engines and require extraordinarily different design parameters.

[I]n exhalation valves for filtering face masks, the speed of opening is not a primary design parameter. There is no incumbent need to rapidly fill or exhaust a combustion chamber. Further, at the airflows and pressure drops that are encountered in a respiratory mask, "bounce" is not an occurring event. Investigators in the exhalation valve art for filtering face masks seek to produce exhaust valves that minimize force to open from the normally closed position. This particular design parameter is not compatible with fast-closing valves that require high forces for rapidly opening and closing. The flow volumes and flap stiffnesses are orders of magnitude higher for valves used in combustion engines as opposed to valves that are used on respiratory masks. For these reasons, a person of ordinary skill in the filtering face mask art would not have found the McKim patent to be

reasonably pertinent to the problems that are encountered in the development of an exhalation valve for a filtering face mask.⁵

In view of this testimony, it is clear that persons of ordinary skill in the exhalation valve art would not have consulted a reference to a reed valve for a two-cycle engine in developing an exhalation valve for a filtering face mask. McKim is not a reference that would have logically commended itself to the attention of a person skilled in designing valves for filtering face masks. There is nothing in the record that indicates otherwise. Thus, McKim cannot be properly relied on as a secondary and combinable reference to the Simpson patent.

Like McKim, French Patent 1,209,475 also has been cited as a secondary reference that is allegedly combinable with Simpson. This patent has been relied on to teach the subject matter of claim 58. Although applicants' attorney is not versed in the French language, it does not appear that the subject matter described in the French patent relates to the field of filtering face masks. It appears that the French patent is describing some type of high-pressure valve that would be used in a field wholly separate from exhalation valves for filtering face masks. Thus, to the extent that the French patent discloses any valve cover, it certainly is not disclosing a valve cover that resides on an exhalation valve — much less an exhalation valve that would be used on a filtering face mask. The record also does not present any evidence that shows why a person of ordinary skill in the field of filtering face masks or exhalation valves would have looked to the high-pressure valve art when designing a new exhalation valve for a filtering face mask. Without such evidence, the teachings of the French patent cannot be combined with those of Simpson.

Additionally, U.S. Patent 4,981,134 to Courtney also has been cited as a secondary reference pertinent to claim 58. Although this reference does reside in the field of filtering face masks, it adds little or nothing to what is lacking in Simpson. Courtney shows a "grill-like spider of radial elements 19." It is apparent from a quick examination of Courtney's Figure 1, that air can easily pass through this structure. It therefore cannot be construed as being fluid impermeable. The valve cover that is recited in claim 58 requires a *fluid impermeable ceiling* that increases in height in the direction of the flexible flap from the stationary portion to the free portion. Courtney discloses radial elements 19, which if examined individually, would be fluid impermeable, but each radial element does not constitute a ceiling. Courtney therefore does not

⁵ Castiglione Affidavit signed November 15, 1999 (copy of Affidavit is attached).

teach or suggest anything that could reasonably be construed as a *fluid impermeable ceiling*. As the Examiner is aware, claims are to be given not simply their broadest construction but rather their broadest *reasonable* construction, interpretation, or meaning that is *consistent* with the specification.⁶ In addition, applicants' claim requires both a ceiling and cross members. The cross members are disposed within the valve cover's opening. Courtney's "grill-like spider of radial elements 19" certainly cannot meet both limitations in applicants' claim. Such a reading would be entirely inconsistent with the construction of the claim. Although Courtney's radial elements 19 could certainly qualify as cross members, they in no way resemble a fluid-impermeable ceiling. Without any teaching or suggestion of this feature, applicants' invention therefore would not have been obvious to a person of ordinary skill under the terms of 35 U.S.C. § 103.

Even if we assume, however, that applicants' claim 58 could possibly be construed such that Courtney's grill-like spider of radial elements 19 qualifies as both a fluid impermeable ceiling and cross members (that are disposed within an opening of the valve cover), the combination of Simpson and Courtney still would not have taught or suggested the present invention because Courtney does not teach a fluid-impermeable ceiling *that increases in height in the direction of the flexible flap from the first end to the second end*.

The first end of applicants' flexible flap is associated with the stationary portion of the flap so as to remain at rest during an exhalation. The second end of applicants' flexible flap is associated with the free portion so as to be lifted away from the seal surface during an exhalation. The second or free end of applicant's flexible flap is also located below the first or stationary end when the filtering face mask is worn. A valve cover is disposed over the flap, which increases in height in a direction that points towards the free end of the flap. Courtney does not teach a filtering face mask that has such a construction. Nor does it recognize the benefits that stem from this construction.

In Courtney, the flexible flap is centrally mounted to the valve by a transversely projecting nub 61. A careful examination of the Courtney valve reveals that the "grill-like spider of radial elements 19" *decreases* in height towards the free end of the flap. Therefore, even if we make the

⁶ *In re Sneed*, 710 F.2d 1544, 218 USPQ 385, 388 (Fed. Cir. 1983) ("It is axiomatic that, in proceedings before the PTO, claims in an application are to be given their broadest reasonable interpretation consistent with the specification, and that claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art."); *In re Reuter*, 651 F.2d 751, 210 USPQ 249, 253 (CCPA 1981).

assumptions spelled out above to construe Courtney's collection of rib elements 19 as a "fluid impermeable ceiling", Courtney's "ceiling" does not increase in height in the direction that points towards the flap's free end. To the contrary, Courtney's valve has its structure 19 decrease in that direction. Thus, Courtney clearly teaches away from applicants' invention.

Even if it were then further assumed that Simpson and Courtney's combined disclosures taught all of the elements of the present invention, despite Courtney's clear teachings to the contrary, applicants' invention still would not have been obvious to a person of ordinary skill because there is no teaching, suggestion, or motivation to combine the pertinent disclosures in each document.

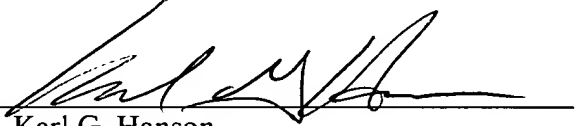
Simpson provides no teaching or suggestion for using Courtney's grill-like spider of radial elements on the flapper-style valve 13 shown in Figure 2 of Simpson. Courtney's grill-like spider of radial elements 19 would more properly be used on Simpson's button-style valve 14 shown in Figure 3, if it was used on either of Simpson's valves. The button-style valve that Simpson discloses in Figure 3 is centrally mounted like the centrally-mounted exhaust valve 35 described in Courtney. The use of a flapper-style valve like the one shown in Figure 2 of Simpson would not be particularly suitable for use with Courtney's grill-like spider of radial elements. As indicated above, the radial elements 19 described in Courtney decrease in height as they move outwardly from the center. This low profile at the end of Courtney's radial elements 19 would hamper opening of a flapper-style valve like the one shown in Figure 2 of Simpson.

For the above reasons, applicant respectfully submits that the obviousness rejection cannot be properly sustained under 35 U.S.C. § 103. Please favorably reconsider this rejection and allow this application at an early date.

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32,900	651-736-7776
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Respectfully submitted,

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B

VERSION WITH MARKINGS TO SHOW CHANGES MADE

Changes to Specification:

Page 7, line 22, between "exhalation." and the word "As" insert a new sentence:

When a wearer of a filtering face mask 10 exhales, exhaled air passes through the mask body 12 and exhalation valve 14. Comfort is best obtained when a high percentage of the exhaled air passes through exhalation valve 14 as opposed to the filter media of mask body 12. Exhaled air is expelled through valve 14 by having the exhaled air lift flexible flap 24 from valve seat 26. Flexible flap 24 is attached to valve seat 26 at a first portion 28 of flap 24, and the remaining circumferential edge of flexible flap 24 is free to be lifted from valve seat 26 during exhalation. The first portion (28) of the flexible flap (24) remains stationary during an exhalation and has a circumferential edge segment that may also remain stationary. As the term is used herein, "flexible" means the flap can deform or bend in the form of a self-supporting arc when secured at one end as a cantilever and viewed from a side elevation (see e.g., FIG. 5). A flap that is not self-supporting will tend to drape towards the ground at about 90 degrees from the horizontal.

Page 11, line 31, after "24" please insert --that is-- and at line 32, between "first" and "portion" insert --stationary--:

FIG. 5 illustrates a flexible flap 24 that is deformed by applying a uniform force to the flexible flap. Flexible flap 24 is secured at a first stationary portion 28 to a hold-down surface 46 and has for a second or free portion suspended there from as a cantilever beam. Surface 46 desirably is planar, and the flexible flap 24 is preferably secured to that planar surface along the whole width of portion 28. The uniform force includes a plurality of force vectors 47 of the same magnitude, each applied at a direction normal to the curvature of the flexible flap. The resulting deformation curve can be used to define the curvature of a valve seat's seal ridge 30 to provide a flexible flap that exerts a substantially uniform force upon the seal ridge.